January 25, 2008

Via E-Mail

Michael D. Shelby, Ph.D.
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RE: National Toxicology Program; Center for the Evaluation of Risks to Human Reproduction; Announcement of the Availability of the Bisphenol A Expert Panel Report

Dear Dr. Shelby:

The North American Metal Packaging Alliance (NAMPA) (formerly the Inter-Industry Group for Light Metal Packaging (IIG)) submits these comments in response to the November 30, 2007, notice announcing availability of, and requesting comment on, the final report entitled "NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A" (CERHR Panel Report) dated November 26, 2007.

NAMPA is vitally interested in the subjects addressed in this report because NAMPA members use epoxy resins derived from bisphenol A (BPA) to manufacture protective polymer coatings for the inner surface of metal food and beverage containers. This critical technology protects the contents of these containers from aggressive food products, thereby assuring a safe, wholesome, and nutritious food supply. Compared to other coating technologies, coatings derived from epoxy resins provide superior adhesion to the metal surface, greater durability, and higher resistance to the wide range of chemistries found in foods and beverages. These attributes are essential to protect the packed food from microbiological contamination, which is a significant food safety issue.

NAMPA strongly supports the comments on the CERHR Panel Report submitted by the Polycarbonate/BPA Global Group of the American Chemistry Council. NAMPA additionally has the following general observations:

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The North American Metal Packaging Alliance is an organization whose objectives are to support risk-based regulations in North America, influence regulation in other geographies, provide customers with needed information regarding well-founded technologies, and advocate risk-based decision-making in technology decisions.



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- The final CERHR Panel Report should be considered authoritative because it is based on a comprehensive review of the entire body of scientific literature on BPA, and because the CERHR Panel is composed of independent experts who did not conduct the research under review and have not advocated any particular position concerning regulation of BPA. The findings of the CERHR Panel are supported by another recent evaluation of BPA prepared by the European Food Safety Authority. In contrast, another evaluation of BPA prepared by a group called the Chapel Hill Consensus is based on a very selective review of the scientific literature, and was coordinated by scientists who have personally done research on BPA and advocated restrictions on BPA use.
- The scientific evidence strongly supports the CERHR Panel's conclusion that there is minimal or negligible basis for any concern that BPA could cause birth defects, accelerated puberty, or prostate effects for pregnant women and fetuses, infants and children, or adverse reproductive effects among adults in the general population. NAMPA shares the CERHR Panel's views regarding the scientific implausibility of any mechanism that would produce endocrine effects at low doses that are not also observed in well conducted studies at higher doses.
- Although the CERHR Panel has expressed "some concern" regarding the neural and behavioral effects reported in some studies of rats and mice at relatively low BPA doses, the Panel also acknowledges that it is not even clear whether these effects should be construed as an adverse toxicological response. Moreover, the Panel stated that the higher dose studies that demonstrate the implausibility of the other low-level effects did not adequately assess neural and behavioral effects.
- The level of BPA appearing in food due to migration of excess monomer from the epoxy coating on metal food and beverage containers is often significantly overstated. Unless an analytical methodology suitable for measuring very low BPA levels in complex matrices is utilized, the reported results can be influenced by interferences from other food constituents. As the CERHR Panel Report documents, much of the sampling to date has been done utilizing Gas Chromatography with Mass Spectrometry (GC/MS), an approach prone to interferences from substances naturally present in food products. High Performance Liquid



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Chromatography with tandem MS (HPLC/MS/MS) is a more reliable approach, but is seldom used due to its cost.

NAMPA appreciates this opportunity to comment on the matters discussed in the CERHR Panel Report.

Respectfully submitted,

[Redacted]

John M. Rost, Ph.D. Chair, NAMPA